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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,883	05/01/2002	Francois Mallet	112062	3896
7590		01/26/2005	EXAMINER	
Oliff & Berridge		LI, BAO Q		
P O Box 19928				
Alexandria, VA 22320		ART UNIT		
		1648		
		PAPER NUMBER		

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,883	MALLET ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>as attached</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Response to Amendment

This is a response to the amendment, paper No. 17, filed 11/05/04. Claims 1-37 have been canceled. Claims 38-43 have been added. Claims 38-43 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Because Applicants canceled all rejected claims 1-11 and filed another set of claims 38-43 that applicants claims that read on the rejected claims 1-11. The previous rejections on claims 1-11 are moot in view of the new ground rejections on the new set of claims.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 38-43 are still rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting the presence of a human endogenous retrovirus W (HERV-W) envelope protein by using polypeptide of SEQ ID NO:1 transfected TELac2 cells to see a syncytial formation, does not reasonably provide enablement for using a cell-cell fusion assay, wherein the cells are transfected with any envelope protein of a human endogenous retrovirus or any protein encoded by a gene located in the chromosome 7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.
3. In response to the previous office action, applicants mainly argue that because the specification discloses a region of amino acid residues 448-538 is critical TM-CYT domain for allowing the protein to bind its receptor, leading to the formation of syncytia and two detail protocols for detection of fusogenic power of the protein, the rejection should be withdrawn.

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4. Applicants' argument has been respectfully considered; however, it is not found persuasive because at first, the particular domain TM-CYT asserted by applicants to be essential is not in the rejected claim(s). Secondly, the broad scope of the claimed envelope protein read on any or all envelope protein or any protein encoded by a gene located at the human chromosome 7 with out such limitation. Applicants only teach that one isolated envelope protein from human endogenous retrovirus W (HERV-W). Applicants do not teach that every envelope protein or any protein encoded by the gene located at the chromosome 7 contain such domain.

5. Because the scope of the claims is so broad and applicants failed to provide enough evidence or teaching to support the broadly claimed envelope protein or protein or any protein encoded by a gene located at the chromosome 7. It still renders undue experimentation for a person with ordinary skill in the art. Therefore, the claims are still rejected.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 38-43 are still rejected under 35 U.S.C. 102(e) as being anticipated by Jacobs et al. (US Patent No. 6,312,921B1) under the same ground as stated in the previous Office Action.

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8. Applicants transverse the rejection and submit while Jacobe teaches to observe a syncytial formation by using the claimed polypeptide, he does not point out that the syncytial formation on the transfected cell is dependent on the presence of at least cell-surface receptor on the cell surface. The new claim 38 has such feature; therefore, the rejection should be withdrawn.

9. Applicants' argument and new claims have been fully considered; however, it is not found persuasive because while Jacob et al do not disclose that the cell comprising a receptor that is necessary for mediating the syncytial formation, the cells used by Jacobs are the same types of cells that applicants claim to be used for the claimed method. Moreover, applicants do not disclose that the syncytial formation assay is conducted by adding the cell surface receptor in the solution as a free molecule rather than expressing it on the cell surface, the cell that inherently expresses the receptor on the cell surface, and mediates the cell fusion. Therefore, the claimed method is still inherently anticipated by the disclosure of Jacobs et al.

10. Regarding this inherency rejection, applicants' attention is directed to Feit et al. (2003, J. Pat. Trade. Off. Soc., Vol. 85, No. 1, pages 5-21), in that article, Feit et al. teach three criteria for analysis whether the prior art is inherently anticipate a claim(s). (1). The most important criterion is certainty. Citing *In re Tomlinson* and *In re Zierden*, Feit et al. state that certainty is established when the reference process necessarily **results** in the claimed process as opposed to a **possibility**. (2) The second criterion is chronology; it will always happen. Feit et al. state that the chronological test is forward chronology. Citing *Eli Lilly and Co. v Barr Laboratories, Inc.*, Feit et al. argue that the claimed result must always be obtained based upon the prior art method. 3) The third criterion is the legal standard. Feit et al., citing *Continental Can*, state that the legal standard is whether the missing descriptive material would be so recognized by a person of ordinary skill in the art as necessarily present in the thing.

11. In the instant case, all claimed cells as disclosed by Jacobs certainly comprises the receptor, and the cell line expressing such receptor will certainly fuse with the cells when they are transfected with the claimed envelope protein.

12. Regarding to the receptor that is a molecule found later to be involved in the fusion, Feit et al. further point out that: If a person having ordinary skill presented with the fact would understand that the prior art inherently disclose a claimed element, the element is anticipated. It

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is irrelevant whether the understanding was apparent at the time of filing the application in question, or first becomes apparent at a later time.

13. Therefore, the claimed invention is still anticipated by the cited reference.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

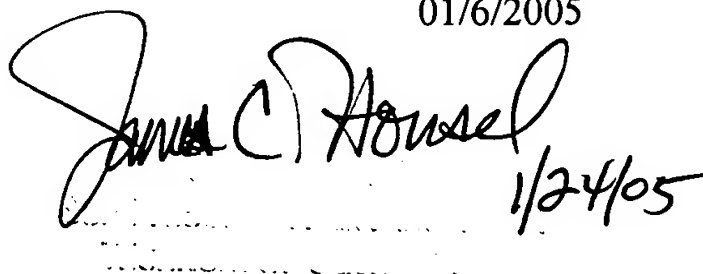
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

01/6/2005

 1/24/05